## 510(k) Summary (as required by 21 CFR 807.92(c)) K112090

JUN - 7 2012

**Manufacturer Name and Address**
Bahadir USA Corp.
275 West Hoffman Avenue
Lindenhurst, NY 11757
Contact: Ismail Kilic
Tel: 631-608-8522

**Submitter / Contact Person**
Bahadir USA Corp.
275 West Hoffman Avenue
Lindenhurst, NY 11757
Contact: Ismail Kilic
Tel: 631-608-8522
Email: info@bahadirusa.com

**Date Prepared**
Revised July 8, 2011
Revised February 27, 2012
Revised April 2, 2012
Revised May 22, 2012

**Name of Device**
BAHADIR STERILIZATION TRAYS (INCLUDING WIDE BODY)

**Classification Name**
Sterilization Wraps, Trays, Containers
Class 2 – KCT

**Predicate Device**
Bahadir – K102146

**Description of the Device**
**Intended Use**

Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized and to allow sterilization of the enclosed medical devices using steam sterilizers. Sterilized devices may be stored and transferred in the container.

The devices included in this submission are to be used with a pre-vacuum cycle of 4 minutes at 270 degrees F with a dry time of 20 minutes.

The devices (natural aluminum color containers and lids) subject to this submission are as follows:

| | | |
|---|---|---|
| Full Size Y111.10W | ¾ Size Y211.10W | ½ Size Y311.10W |
| Full Size Y111.13W | ¾ Size Y211.13W | ½ Size Y311.13W |
| Full Size Y111.15W | ¾ Size Y211.15W | ½ Size Y311.15W |
| Full Size Y111.20W | | ½ Size Y311.20W |
| Full Size Y111.26W | | ½ Size Y311.26W |
| Full Size Y110.62W | | |
| Full Size Y110.68W | | |
| Full Size Y111.62W | | |
| Full Size Y111.68W | | |
| **(Full Size Max Load Wt. 24.75 lbs including basket & instruments)** Lumen Size min 1mm diameter X 300mm length | **(¾ Max Load Wt. 12.5 lbs including basket & instruments)** Lumen Size min 1mm diameter X 200mm length | **(½ Size Max Load Wt. 9.25 lbs including basket & instruments)** Lumen size min 1mm diameter X 200mm length |

**DESCRIPTION**

The devices included in this submission are to be used with a pre-vacuum cycle of 4 minutes at 270 degrees F with a dry time of 20 minutes.

The devices subject to this submission are as follows:

| | | |
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| Full Size Y111.10W | ¾ Size Y211.10W | ½ Size Y311.10W |
| Full Size Y111.13W | ¾ Size Y211.13W | ½ Size Y311.13W |
| Full Size Y111.15W | ¾ Size Y211.15W | ½ Size Y311.15W |
| Full Size Y111.20W | | ½ Size Y311.20W |
| Full Size Y111.26W | | ½ Size Y311.26W |
| Full Size Y110.62W | | |
| Full Size Y110.68W | | |
| Full Size Y111.62W | | |
| Full Size Y111.68W | | |

The devices are composed of anodized aluminum (this does not include colored anodized lids).

## Comparison to Predicate Devices

The containers are the identical design, materials, sterilization cycle, and indications for use. The only difference is the dimensions (sizes).

| Feature | Bahadir | Bahadir K102146 |
|---|---|---|
| Intended Use | Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized. Containers allow sterilization of the enclosed medical devices, including surfaces and lumens, using high vacuum steam sterilizers for 270 F for 4 minutes with 20 minutes (minimum) dry time. | Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized. Containers allow sterilization of the enclosed medical devices, including surfaces and lumens, using high vacuum steam sterilizers for 270 F for 4 minutes with 20 minutes (minimum) dry time. |
| Material | Aluminum Alloy, stainless steel handles, silicone seal, paper filter | Aluminum Alloy, stainless steel handles, silicone seal, paper filter |
| Filter | Paper Filter | Paper Filter |
| Sterilization Method | Steam | Steam |
| Configurations / Dimensions | Includes:<br><br>Full Size Y111.10W (580x280x100mm)<br>Full Size Y111.13W (580x280x135mm)<br>Full Size Y111.15W (580x280x150mm)<br>Full Size Y111.20W (580x280x200mm)<br>Full Size Y111.26W (580x280x260mm) | Includes ½ size, ¾ size, and full size<br><br>Full size<br>580mm x 280mm x 200mm<br>580mm x 280mm x 150mm<br>580mm x 280mm x 135mm<br>580mm x 280mm x 100mm |

| | | |
|---|---|---|
| | Full Size Y110.62W (600x400x120mm)<br>Full Size Y110.68W (600x400x180mm)<br>Full Size Y111.62W (600x400x120mm)<br>Full Size Y111.68W (600x400x180mm)<br>¾ Size Y211.10W (465x280x100mm)<br>¾ Size Y211.13W (465x280x135mm)<br>¾ Size Y211.15W (465x280x150mm)<br>½ Size Y311.10W (285x280x100mm)<br>½ Size Y311.13W (285x280x135mm)<br>½ Size Y311.15W (285x280x150mm)<br>½ Size Y311.20W (285x280x200mm)<br>½ Size Y311.26W (285x280x260mm | ¾ Size<br>465mm x 280mm x 150mm<br>465mm x 280mm x 135mm<br>465mm x 280mm x 100mm<br><br>½ size<br>285mm x 280mm x 200mm<br>285mm x 280mm x 150mm<br>285mm x 280mm x 135mm<br>285mm x 280mm x 100mm |
| Perforation | The units included in this submission include perforated lids and both non-perforated and perforated bottoms. | The units included in this submission include perforated lids and non-perforated bottoms. |
| Air Permeance | Permits entry of sterilization agent and prevents microbial migration during storage. | Permits entry of sterilization agent and prevents microbial migration during storage. |
| Intended to be re-used | Yes | Yes |
| Sealed | Yes | Yes |
| Conformance to AAMI ST 77 | Yes | Yes |
| Gasket | Silicone Based (gray color) | Silicone Based (gray color) |
| Handles | Wider handles with silicone holder | Wider handles with silicone holder |
| Cycle Parameters | 270 F at 4 minutes 20 minutes drying | 270 F at 4 minutes 20 minutes drying |
| Use with cannulized instruments | Yes | No |

The differences are as follows:

- The only difference is the dimensions (wide body size).
- Includes non-perforated and perforated bottom
- Can be used with cannulized instruments

**Non-Clinical Tests Performed**

The subject devices were subjected to sterility testing and performance testing.

**Summary**

In conclusion we believe the devices are substantially equivalent to the predicate devices and do not introduce new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Ismail Kilic
President
Bahadir USA Corporation
275 West Hoffman Avenue
Lindenhurst, New York 11757

JUN - 7 2012

Re: K112090
Trade/Device Name: Bahadir USA Sterilization Trays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: May 29, 2012
Received: May 31, 2012

Dear Mr. Kilic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

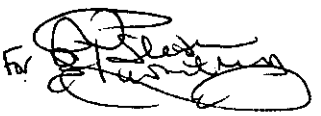
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K112090

Device Name: Bahadir USA Sterilization Trays

Indications For Use:

Intended for use in hospitals and healthcare facilities to contain other medical devices that are to be sterilized and to allow sterilization of the enclosed medical devices using steam sterilizers. Sterilized devices may be stored and transferred in the container.

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use X (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie Wilson

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices



510(k) Number: K112090